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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,730	DAVIS ET AL.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36 and 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Applicant's amendment filed 9 May 2005 has been entered. Claims 1-3 are currently amended. Claims 37-55 and 57-62 are canceled. Claims 1-36 and 56 are currently pending in this application.

Withdrawn Rejections

2. Rejection of claims 1-36 and 56 under 35 USC 112, second paragraph except for the rejection of claims 1 and 3, have been withdrawn.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-36 and 56 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification does not provide a junction connecting first and second conduits. It is noted the original specification describes a "T" of Fig. 6, at page 28, lines 13-20. The "T" region is merely described as a region of the sensor channel in the vicinity of a

transecting conduit to fill with analysis liquid, but does not provide a junction connecting the first and second conduit. Regarding claim 29, the original specification does not provide for one mechanical and electrical connections, and therefore does not provide one or more mechanical and electrical connections.

2. Claims 1, 3-36 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 1 and 3, it is unclear whether the fluid is displaced from a second to a first conduit because the sample holding chamber is recited as retaining the sample and the second conduit is also recited as retaining the sample. It is unclear whether the sample holding chamber is within the second conduit so the sample flows from the second conduit to the first conduit and also from the first conduit to the second conduit.

Claim Rejections - 35 USC § 102

1. Claims 1-3, 5-8, 12-21, 30, 31, 34-36 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Kapur et al. (US 6,548,263).

Kapur et al. teach a single-use (col. 12, line 66-col. 13, line 4) cartridge comprising: a sample holding chamber for receiving and retaining a sample (capillary, 024, receives and retains a sample until pushed into the first conduit, 030, Fig. 8; col. 12, lines 34-45); a first conduit connected to the sample holding chamber (030 and 008, Fig. 8; col. 20, lines 40-48); at least one analyte sensor, wherein the sensor comprises an analyte-responsive surface and the surface is within the first conduit (008, Fig. 1b; col. 12, lines 46-56); a second conduit for retaining a fluid, the second conduit connected to the first conduit (032, Fig. 8; col. 20, line 64-col.21, line 4); a valve connected to an opening in the first conduit, wherein the valve is closed by contact with the

sample (500, Fig. 36; col. 20, lines 48-52); means for inserting a single or plurality of air segments into the first and second conduit (740, Fig. 41; col. 20, lines 12-40; col. 31, lines 46-49; col. 33, line 65-col. 34, line 11), wherein the means comprises a plurality of electrodes operably connected to a current source (col. 28, lines 12-40); a pump capable of displacing the sample from the holding chamber into the first conduit, the pump further capable of displacing the fluid from the second conduit into the first conduit (740, Fig. 41; col. 20, lines 12-40); and a third conduit connecting the second conduit to an overflow chamber (300, Fig. 29 and 41; col. 28, lines 37-40).

Regarding claims 13-16, Kapur et al. teach a closable valve comprising a dry sponge coated with a fluid impermeable layer, a flap capable of blocking the valve and held open by a dry gelling polymer (col. 30, lines 40-65). Kapur et al. also teach at least one constriction to control fluid flow within the first and second conduits (col. 26, lines 28-53). Kapur et al. further teach the second conduit further comprising a valve responsive to hydrostatic pressure (col. 33, lines 43-47), and the valve comprising a constriction having a fluid-contacting surface comprising a hydrophobic surface (col. 26, lines 28-53).

With respect to claims 18, Kapur et al. teach the pump being an electrodynamic pump (electrokinetic pump; col. 28, lines 12-40).

Regarding claims 19-21, Kapur et al. teach an analyte-responsive surface comprising an antibody (col. 18, lines 30-63) and a portion of at least one conduit further comprises at least one dry reagent capable of dissolving in the fluid or sample (col. 48, lines 28-53), wherein the dry reagent is an antibody-enzyme conjugate (col. 58, lines 52-67).

With respect to claims 30 and 31, Kapur et al. teach an analyte sensor formed on a substantially planar surface (col. 10, lines 1-6). Kapur et al. also teach a surface coating that decreases non-specific binding of a substance (col. 2, lines 40-43).

With respect to claims 34-36, Kapur et al. teach mobile magnetic microparticles comprising a magnetic field for localizing the microparticles adjacent to at least one sensor (600, Fig. 37; col. 34, line 61-col. 35, line 9). Kapur et al. further teach a filter element interposed between the sample holding chamber and the analyte sensor and adjacent to the sensor (filter-76,78,80, Fig. 13; sensor-82, Fig. 13).

Regarding claims 56, Kapur et al. teach the sample holding chamber further comprising a closure means (valve, col. 20, lines 48-52).

Claim Rejections - 35 USC § 103

2. Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kapur et al. (US 6,548,263) in view of Zelin (Us 5,821,399).

Kapur et al., as applied to claims 1-3, teach a cartridge for sensing at least one analyte, but fail to teach at least one sensor capable of detecting an air-liquid interface.

Zelin teaches a cartridge comprising air segments inserted into conduits (col. 3, lines 34-42) and a conductivity sensor capable of detecting an air-liquid interface (col. col. 4, lines 40-67), in order to displace calibrating fluid and separate calibrating fluid from a blood test sample.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the cartridge of Kapur et al., a conductivity sensor as taught by Zelin, in order to ensure a constant volume of test fluid sample passing over the sensors to

increase the consistency and reliability of the output measurements made by each sensor of the sensing device of the fluid system.

3. Claims 10 and 11 rejected under 35 U.S.C. 103(a) as being unpatentable over Kapur et al. (US 6,548,263) in view of Opalsky et al. (US 6,438,498).

Kapur et al., as applied to claim 1, teach a cartridge for sensing at least one analyte, but fail to teach a means for metering.

Opalsky et al. teach a means for metering involving a capillary stop in a first conduit in order to adequately fill a sensor channel (col. 10, lines 38-col. 11, line 10).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the cartridge of Kapur et al., a means for metering as taught by Opalsky et al., in order to regulate the amount of volume entering the second conduit.

4. Claims 22-26, 28-29 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kapur et al. (US 6,548,263) in view of Zier et al. (US 4,919,141).

Kapur et al., as applied to claims 1-3 and 20-21, teach a cartridge for sensing at least one analyte comprising a dry reagent being an antibody-enzyme conjugate, but fail to teach a specific enzyme.

Zier et al. teach an enzyme glucose oxidase (col. 3, lines 35-44), in order to coat a measurement electrode for an implantable sensor.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the cartridge of Kapur et al., an enzyme of glucose oxidase, in order to detect analyte in blood or tissue liquid.

With respect to claim 32, Zier et al. teach an enzyme and a substrate capable of regenerating a product consumed by contact with the at least one analyte sensor, whereby a signal from the sensor is increased (col. 7, line 63-col. 8, line 13).

Regarding claims 23 and 33, Zier et al. also teach a substrate of D-glucose (col. 7, line 63-col. 8, line 5).

With respect to claim Kapur et al. also fail to teach an analyte sensor being an immunosensor.

Zier et al. teach an immunosensor in order to amperometric measurements in body liquids (col. 4, lines 54-62).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the cartridge of Kapur et al., an immunosensor as taught by Zier et al., in order to determine insulin amount values in a biological fluid of blood.

Regarding claims 25, 28 and 29, Zier et al. teach the blood fluid comprising a substrate for an antibody-enzyme conjugate (col. 6, lines 4-8) wherein the substrate is cleaved to produce an electroactive product (col. 7, line 63-col. 8, line 13). Zier et al. also teach the analyte sensor being an amperometric sensor with a plurality of mechanical and electrical connections (col. 7, lines 45-62).

5. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kapur et al. (US 6,548,263) in view of Zier et al. (US 4,919,141) further in view of Grundig et al. (US 6,221,238).

Kapur et al. in view of Zier et al., as applied to claim 2, teach a fluid comprising a substrate for an antibody-enzyme conjugate wherein the substrate is cleaved to produce an electroactive product, but fail to teach the substrate being ferrocene.

Grundig et al. teach a ferrocene substrate in order to provide a redox-active label of an antigen (col. 1, lines 58-62).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the cartridge of Kapur et al. in view of Zier et al., a ferrocene substrate as taught by Grundig et al., in order to modify increase the sensitivity of amperometric indication of an electrode comprising glucose oxidase.

Response to Arguments

6. Applicant's arguments and amendments, see page 6, filed 9 May 2005, with respect to rejection of claims 1-36 and 56 under 35 USC 112, second paragraph have been fully considered and are persuasive. The rejection of claims 1-36 and 56 under 35 USC 112, second paragraph has been withdrawn. Regarding the rejection of claims 1 and 3, the rejected claims 1 and 3 fail to indicate that fluid starts in the second conduit. It is unclear whether the holding chamber is the same as the first conduit, and whether the pump means displacing the sample from a holding chamber to a first conduit is the same displacement as from a second conduit to a first conduit.

7. Applicant's arguments filed 9 May 2005 have been fully considered but they are not persuasive.

8. Applicant argues Kapur et al. fail to teach analyte sensors. However, Kapur et al. teach a binding-responsive surface at column 12, lines 46-56. A binding-responsive surface encompasses an analyte sensor because the surface senses a specific analyte upon binding. Claims 1, 2 and 3 do not exclude a external interrogation.

9. Applicant argues that the conduits of Kapur et al. are joined in a linear fashion, while the first and second conduit join at a "T" junction. However, it is noted that the features upon which

applicant relies (i.e., a "T" junction) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the joining of the first and second conduits of Kapur et al. form a junction even though the conduits are joined in a linear fashion.

10. In response to applicant's argument that the valve taught by Kapur et al. is not closed by contact with a sample or liquid, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Claims 2 and 3 merely recite the product limitation of a valve connected to an opening in the first conduit. Since Kapur et al. teach this product limitation, and the valve in the instant application does not appear to require any further product limitations in order to be closed by contact with the sample, the valve of Kapur et al. would be capable of being closed by contact with a sample.

11. Regarding claim 13, applicant argues that Kapur et al. fail to teach a flap valve held open by a soluble compound or polymer. Kapur et al. teach a valved manifold containing a dry porous gelling silica (col. 30, lines 30-39), in order to provide a negative pressure pump. The dry porous gelling silica acts as a valve by allowing liquid to flow and then acting as a valve by blocking fluid from entering a waste reservoir after becoming saturated (col. 30, lines 60-62).

With respect to applicant's argument that Kapur et al. fails to teach valve closure enabling one pump means to move both the sample and a second liquid sequentially over the analyte sensor array, such a limitation is not recited in the rejected claims.

12. Applicant argues that Kapur et al. fail to teach air segments in the context of two conduits joined at a junction and by the specific means of claim 12. However, as described above, Kapur et al. teach a first and second conduit joined at a junction in a linear fashion, and describe a means for inserting air segments into a channel (col.). Furthermore, at column 28, line 20, Kapur et al. teach an electrokinetic pump to move liquid through a channel or used as a negative pressure pump. At column 33, line 65, Kapur et al. teach negative pressure methods to introduce air segments into a channel. Therefore, the electrokinetic pump is also used as a negative pressure to introduce air segments into a channel.

13. With respect to independent claims 1, 2 and 3, applicant argues that Kapur et al. fail to disclose a pump means, which is capable of displacing the fluid from the second conduit into the first conduit through a junction where the second conduit is for retaining a fluid. However, Kapur et al. teach a pump which is capable of controlling fluid flow within a microfluidic device (col. 7, line 64). Although Kapur et al. do not specifically teach movement of fluid from the second conduit back into the first conduit, such a limitation is directed to an intended use of the product and does not appear to recite any further product limitations. Since Kapur et al. teach the recited product limitations for a cartridge, the pump of Kapur et al. would be capable of moving fluid from a second conduit back into a first conduit.

14. In response to applicant's argument on page 8 regarding claim 12, that the references fail to show certain features of applicant's invention, it is noted that the features upon which

applicant relies (i.e. a plurality of electrodes that are not sensors used for making a determination) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

15. Regarding claim 17, applicant argues a third conduit connects the second conduit to an overflow chamber, applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

16. Applicant argues the citation at column 30, lines 40-65 address a waste reservoir filled with a porous medium, which are not addressed in claims 13-16. However, such limitations are not excluded from claims 13-16. Applicant also argues that Kapur et al. fail to teach a constriction. However, it is apparent from Figure 8 that a constriction occurs in the conduit between the first conduit, 30, and second conduit, 32, because the channel widens before the second conduit and the constriction occurs as the channel narrows into the second conduit.

17. Regarding claims 30 and 31, applicant argues Kapur et al. do not mention an analyte sensor at column 10. However as described above, Kapur et al. teach an analyte sensing surface, which is an analyte sensor. Applicant further argues that Kapur et al. fail to teach decreasing non-specific binding of substances. However, decreasing non-specific binding of certain cells, refers to non-specific binding of types of cells, which encompasses decreasing non-specific binding of substances.

18. With respect to claims 34-36, applicant argues Kapur et al. fail to teach magnetic particles that interact with the analyte. However, the mobile microparticles of Kapur et al.

interact with the analyte in that the microparticles block the movement of analyte through the channels. Furthermore, the microparticles are localized to the sensor when a magnetic field is applied in order to block a channel.

19. Regarding claim 36, applicant argues that Kapur et al. fail to teach filter elements capable of catching microparticles. However, it is noted that this limitation is not recited in the rejected claim. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

20. Applicant's arguments regarding claims 4, 9, 10, 11 and 27 are not persuasive because the rejected claims are anticipated by Kapur et al.

21. With respect to claim 24, applicant argues Zier et al. fail to teach an immunosensor because Zier et al. is silent on the use of antibodies. However, Zier et al. teach enzyme sensors at column 6, lines 58-60, which encompasses an immunosensor. Claim 24 does not specifically require an immunosensor that detects antibodies. Claim 25, requires a substrate for an antibody-enzyme conjugate, which is glucose oxidase, but does not specifically require an antibody-enzyme conjugate.

Conclusion

No claims are allowed.

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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